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WITNESS my hand this
Twenty-eighth day of August 2000

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APPARATUS FOR OBTAINING BIOLOGICAL SAMPLES

This invention relates to an apparatus for obtaining biological samples from the internal cavity of human organs.

More particularly the invention relates to a syringe-type apparatus for obtaining fluid and cell samples from the human female reproductive system.

Women aged between 45 and 60 years of age appear to be more susceptible than other age groups to cellular abnormalities of the reproductive system. The procedures currently employed to obtain samples may cause discomfort, inconvenience and are prolonged procedures may be embarrassing for most women.

For many years the so-called "Pap" smear tests have been employed to detect abnormal cells in the cervix. However, to examine the internal lining of the uterine cavity, or endometrium, a more invasive diagnostic biopsy or curettage procedure is employed. The biopsy procedure may be done in a doctor's surgery but curettage involves admitting the patient to hospital and the removal of tissue under anaesthetic. These procedures remove cells from the endometrium that require to be assessed by a pathologist.

A new and simpler procedure is now being trialed that tests for certain enzymes and other biological substances produced by the cells of the internal lining of the uterus. Samples are obtained by flushing the uterine cavity with saline solution and conducting tests on the wash-saline. The procedure does not require anesthetics or admission to hospital and can be conducted in the surgery by a general practitioner.

However the present sampling catheter and syringe are unsatisfactory due to excessive leakage of the wash-saline during the procedure. Moreover the wash samples often contain blood and other contaminating cells that need to be removed by centrifuging the wash-saline to obtain a cell-free supernatant. In addition, the operator cannot be sure of the position of the catheter in the uterus or of the efficacy of irrigation of the uterine cavity. The principal objectives of the invention are therefore to provide effective means of controlling the position of the catheter and of irrigating and draining the uterine cavity. A further objective is to always obtain a cell-free wash-saline. A subsidiary outcome would be that the cells that are removed from the washings could be used for detecting abnormal cells.

It is also desirable to reduce the time and the discomfort associated with these procedures for the patient and so it is a further objective of the invention to obtain the required samples from both the cervix and uterus in a single procedure.

To improve the efficacy of irrigation and subsequent aspiration of the wash-saline, an extendible/retractable catheter is attached to the syringe plunger rod. Initially the first part of the catheter is inserted into the cervical canal. As the plunger is depressed, the catheter automatically extends into the uterine cavity, simultaneously spraying the whole of the endometrial lining with wash-saline. In the reverse manner, as the plunger is drawn back the catheter retracts, sucking back or aspirating the wash-saline that in turn passes into the apparatus body. The catheter will be manufactured of soft plastic materials, commonly employed for similar applications, to avoid damaging the uterine lining. Markings on the plunger rod will indicate the depth of penetration of the catheter into the uterine cavity, measured from the cervix entrance.

Samples from the uterine cavity often contain blood and other cells that can render the sample unsuitable for testing. This is particularly so where a considerable period of time may elapse between sampling and testing, as for example, where there is a considerable distance between the place of sampling and the testing laboratory. Therefore another object of the invention is to filter out any blood cells present in the wash-water before it enters the body of the syringe apparatus. This is achieved by a fitting a circular filter over the holes around that part of the catheter adjacent to the plunger head.

The filter is capable of trapping blood cells and other contaminating materials so preventing them from passing into the apparatus body during recovery of the wash-saline. As blood cells are around 7μm (seven millionths of a meter) in size, the filter's pores will be sized to trap all materials larger than about 5μm. It may be desirable to examine these materials and so the filter will be able to be removed from the catheter on completion of the procedure.

The apparatus body and plunger will be manufactured from the appropriate plastic or similar materials presently used for syringes and other medical apparatus.

A further object of the apparatus is to facilitate the recovery of saline used for irrigating the uterine cavity. In an alternative arrangement of the apparatus of the invention a coil spring is fitted over the plunger rod. The spring pushes the plunger head back after irrigation of the uterus, thus aspirating the wash-saline into the syringe body via the catheter. The coil spring could be manufactured from stainless steel or similar, although other non-corroding materials such as plastics or a combination of these may also be suitable.

As aforementioned, it is imperative that damage to the lining of the uterus is avoided and to ensure this, a soft catheter that will bend on contact with the uterus walls is used. The aforementioned firmly fitting coil spring will prevent buckling of the catheter within the syringe body during the procedure.

According to the present invention there is provided an apparatus to which is attached an extendible/retractable flexible catheter and a cervical brush. The apparatus provides means of the storage of sterile saline water and of the subsequently recovered uterine washings. The catheter provides a means of introducing and spraying the saline water over the full length of the uterine cavity and the recovery of the uterine washings.

The removable two-part brush attaches to the body of the syringe and simultaneously removes ecto and endo cervical cell samples. Preferably the two-part brush is capped with a soft cervical plug to prevent uterine washings reaching and contaminating the brush.

Several other arrangements of the invention are obvious to those trained in the art. In particular, the omission of the cell brush in cases where only samples from the uterine cavity are needed and the inclusion of the cervical canal plug only. There are two types of cervical plug proposed and these are illustrated in figures 6 and 7.

In further possible arrangements of the invention the saline is pre-packed in the apparatus as shown in figure 8. The catheter end of the apparatus is sealed with a screw-on cap 20 that is removed before commencing the sampling procedure. After the procedure is completed, the said cap is replaced and, taking care not to spill the contents, the top seal and handle 12 is unscrewed and the plunger and catheter withdrawn. The top seal 12 is replaced by a screw cap supplied with the kit and so the contents are sealed in the apparatus body ready for dispatch for testing.

The filtering device may be removed by pulling the catheter out of the plunger head and slipping the filter off the end of the catheter.

The apparatus of the invention may also find application in other areas of medical practice where it is necessary to obtain samples of internal body fluid or cells or tissue.

The preferred arrangement of the apparatus and its method of use will now be described further with reference to the following drawings in which:

Figure 1 shows the sterile apparatus packed in a casing preparatory to use.

Figure 2 shows the syringe apparatus with the casing removed and the syringe body filled with saline solution.

Figure 3 shows the apparatus positioned for the irrigation procedure and the flexible catheter extending and spraying saline solution into the uterine cavity as it progresses.

Figure 4 shows the flexible catheter withdrawing and aspirating the washings into

the apparatus body. When fully withdrawn, the rod 4 is rotated by hand so that the brush 5 can obtain the cervical cell samples.

Figure 5 shows washings being transferred to a test tube for dispatching to a laboratory for analysis.

The following figures illustrate other arrangements of the apparatus.

Figures 6 and 7 show arrangements of the apparatus for the uterine cavity washing procedure with the brush omitted and a soft tapered plug 13 or 19 added.

Figure 8 illustrates an arrangement of the invention where the apparatus body is pre-loaded with saline solution or other fluid and following the procedure acts as the sample container.

Figure 1 shows the preferred arrangement of the apparatus of the invention. The apparatus is enclosed in an outer casing 1 to keep it sterile before use. The apparatus is removed from the said casing by unscrewing the top 14 of the casing. The apparatus body 2 is enclosed at both ends by bottom seal 10 and combined top screw seal and handle 11. The said body is typically about 10 cm long in overall length and about 1.25 cm in diameter.

Plunger rod 4 is of solid section and commences at handle 12, passes through seal and handle 11 and is fastened into plunger head 3. The recovered washings can be removed from the syringe body 2 by unscrewing combined top seal and handle 11.

The flexible catheter 6 is also fastened to plunger head 3 and so moves both longitudinally and rotationally with plunger rod 4. A filter 9 is fitted around the end of the catheter 6 adjacent to plunger head 3 and covers the holes 15 located around the said catheter circumference. The said catheter moves freely through a watertight hole in bottom seal 10. The free end of the said catheter 6 has a central hole together with series of holes 7 located around its circumference to facilitate irrigation and aspiration.

The cell brush 5, shown in figures 1 to 5, fits over the flexible catheter 6 and is secured to the syringe cap10. The catheter 6 to moves freely through it. The two-part brush has an the outer part about seven millimeters in length and four millimeters in diameter consisting of radial projecting hairs capped with a soft plug 8. The other part of the brush is about seventeen millimeters in diameter and consists of longitudinally inclined projecting hairs.

The purpose of each portion of the apparatus described above will now be explained with reference to Figure 2 to 5 below.

To fill the apparatus with saline solution, the outer casing 1 is removed and the

catheter 6 inserted into a container of saline. The plunger handle 12 is then drawn away from combined top seal and handle 11. This movement transfers to the plunger head 3 and the catheter 6 through the plunger rod 4 thus reducing the pressure in the syringe body 2 and so draws the saline solution into the body of the apparatus 2 via holes 7 and 15 in the catheter 6 and through filter 9. The said catheter is also withdrawn into the said body 2 by this action leaving only a short length protruding from the said body 2. Figure 2 shows the apparatus following this action.

The apparatus is now ready for the uterine irrigation and draining procedure. To conduct the procedure, the vagina is held open with a speculum and the apparatus is positioned in the vagina with the short protruding length of the said catheter, plug 8 and portion of brush 5 inserted into the cervix. The plunger handle 12 is gently pressed in, causing the end of the catheter 6 to move into the uterus and at the same time to spray the endometrial lining of the uterus with saline water 16 via holes 7. This process is illustrated in Figure 3 and is continued until the whole length of the uterus has been irrigated, when the catheter 6 will be extended in the manner shown in Figure 1.

Markings on the plunger rod 4 indicate the depth of insertion of the said catheter in the uterus. The maximum length of the catheter, as measured from the cervical entrance, is about 7 cm. If the uterine cavity is shorter than this then the soft catheter will bend and so not damage the lining. Usually the operator will notice that resistance to forward motion has increased, indicating that the catheter 6 has reached the top of the uterus.

With the apparatus still firmly plugging the cervix, the handle 12 is slowly drawn back, assisted by the spring 21, withdrawing the said catheter 6 and at the same time aspirating the uterine wash-water 18 into the said catheter 6 via holes 7. The washings 18 pass up the said tube 6 to its end, where they pass through holes 15 and filter 9, the latter removing any blood cells and other fine material from the said washings, and into apparatus body 2. Figure 4 illustrates the position of the apparatus during this process. The spring 21 is shown in figure 2 for clarity.

With the handle 12 fully drawn back, the apparatus is rotated using the plunger rod 4 to rub the brush parts in and against the cervix to obtain the ecto and endo cervical samples. The apparatus is removed from the vagina and the speculum released to complete the sampling procedure.

The combined seal and handle 11 are then unscrewed from the apparatus body 2 to allow the filtered washings 18 to be poured into a test tube17 that is then capped ready to be sent to a testing laboratory. This is illustrated in figure 5.

The cervical samples are taken from the brush parts 5 by smearing on microscope slides for examination.

Where only a uterine cavity sample is required, the brush 5 is omitted and a soft flat plug 13 is attached to the seal 10 as illustrated in Figure 6. The said plug 13 is firmly pressed against the cervix to prevent leakage during the uterine irrigation and aspiration procedure described above.

In an alternative arrangement suitable in general for women who have borne children, a longer, slimmer plug 19, illustrated in figure 7, is inserted into the cervical canal to prevent leakage of the saline wash-water 16. The hollow plug is attached to seal 10 and the catheter 6 moves freely through it. The longer leakage path from the syringe body 2 to the end of the plug 13 assists in reducing leakage during irrigation with any such leakage into the uterine opening. Typically this plug is 7 mm long and 4 mm in diameter and is manufactured from soft compressible material.

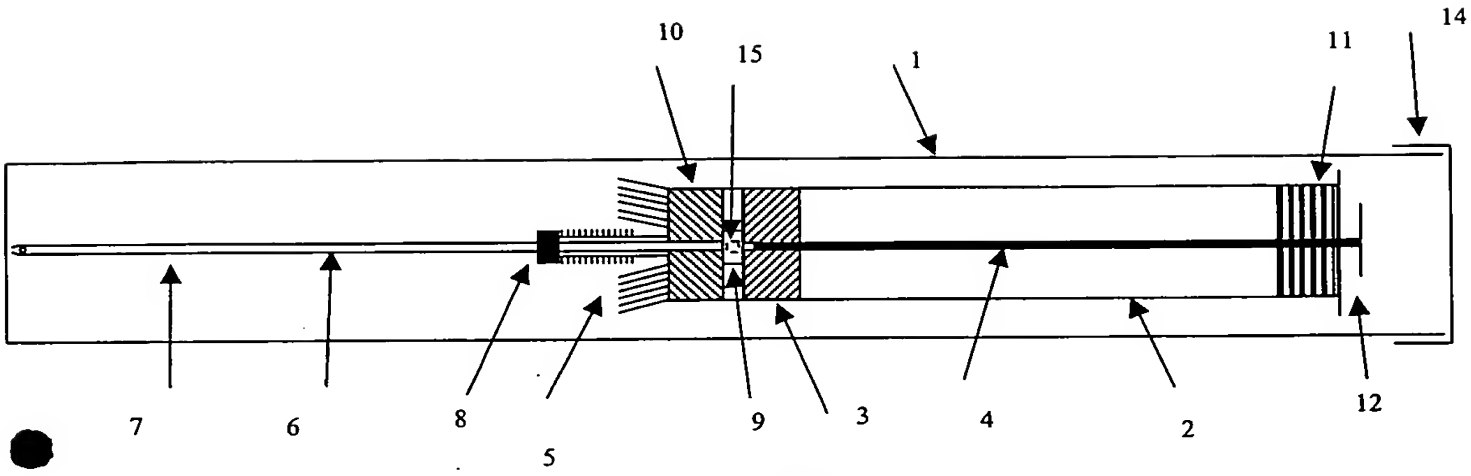

Figure 1

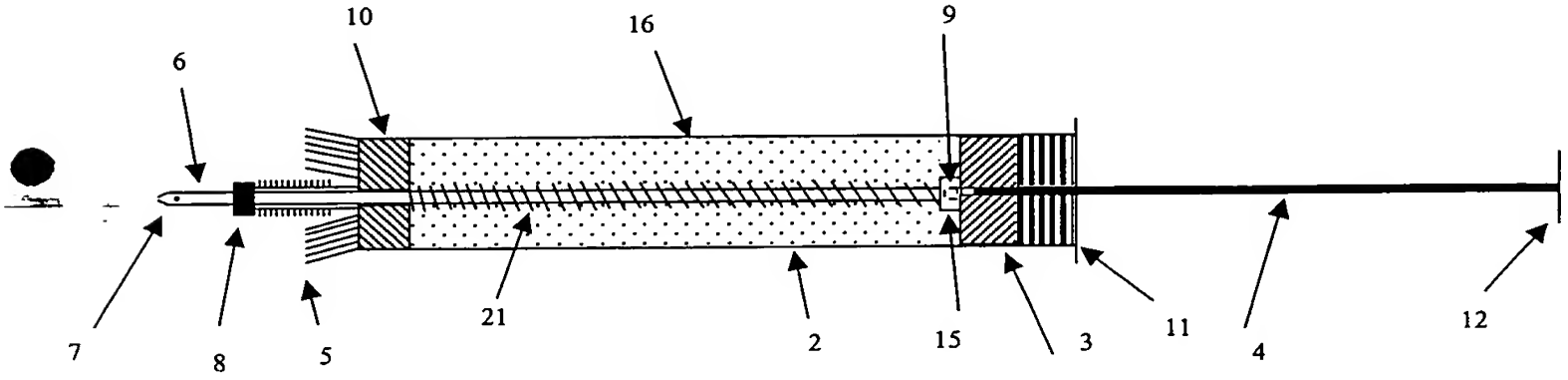

Figure 2

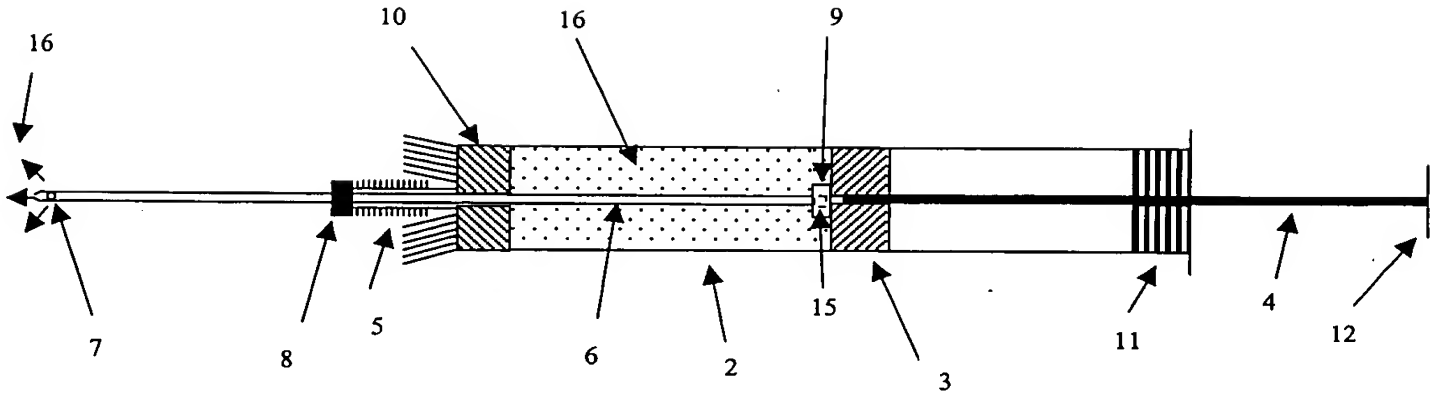

Figure 3

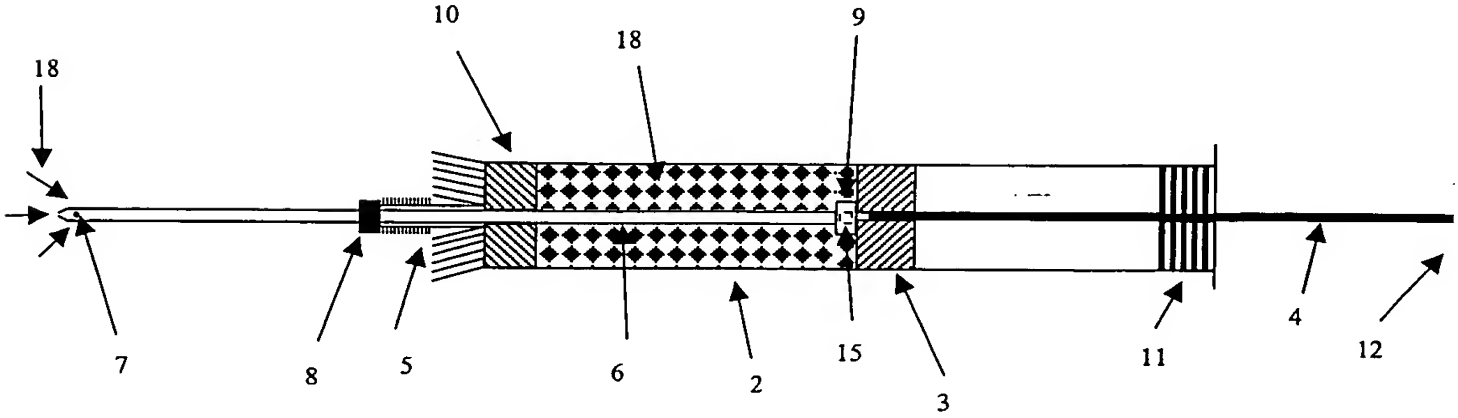

Figure 4

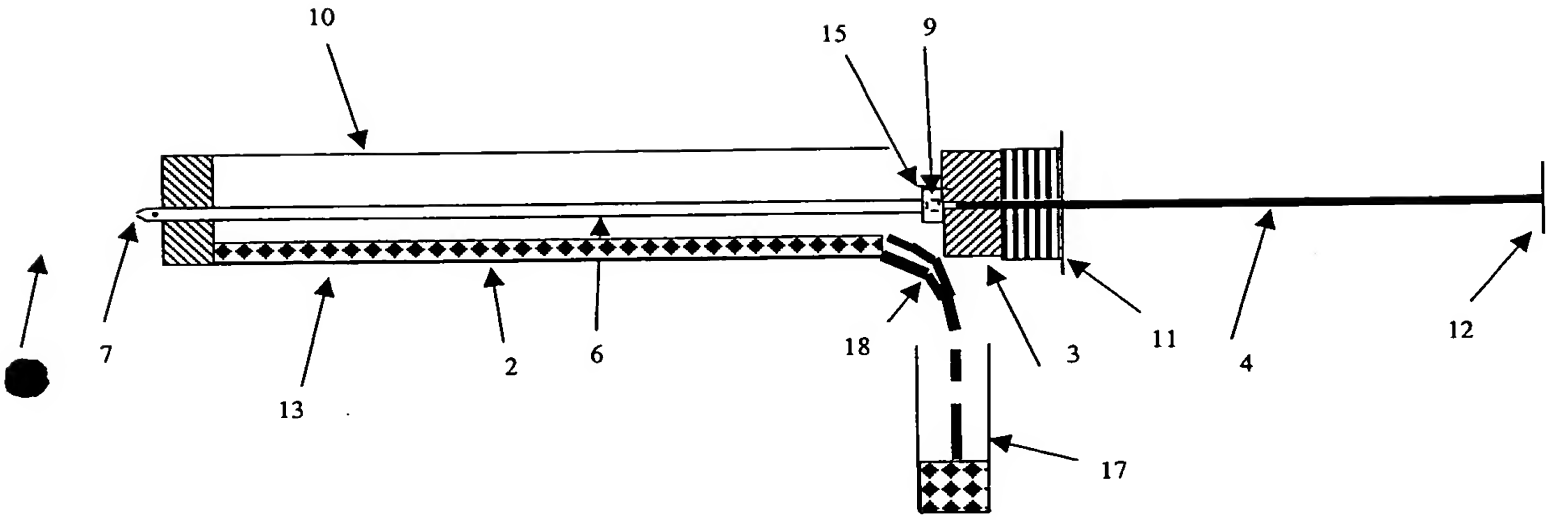

Figure 5

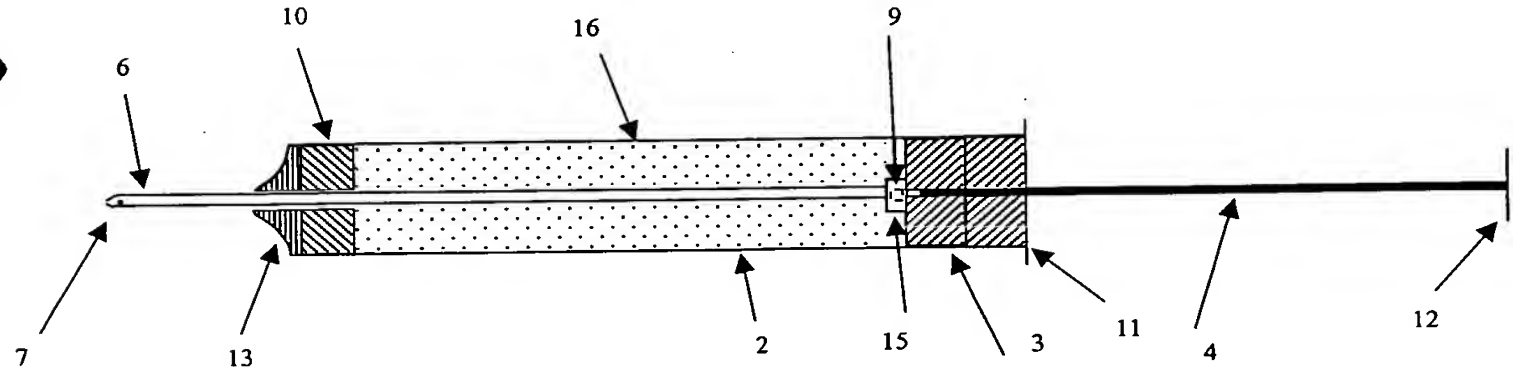

Figure 6

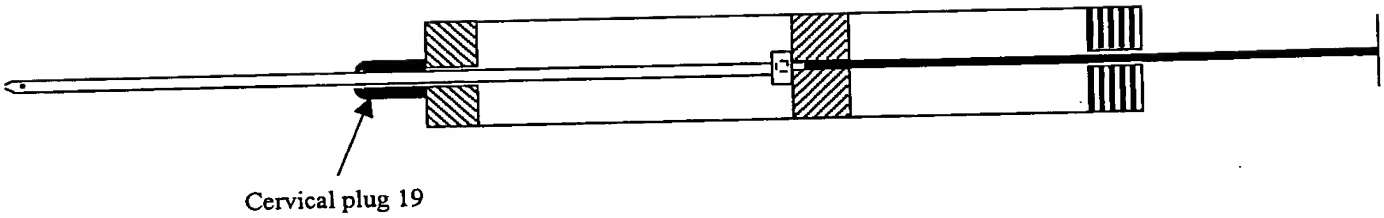

Figure 7

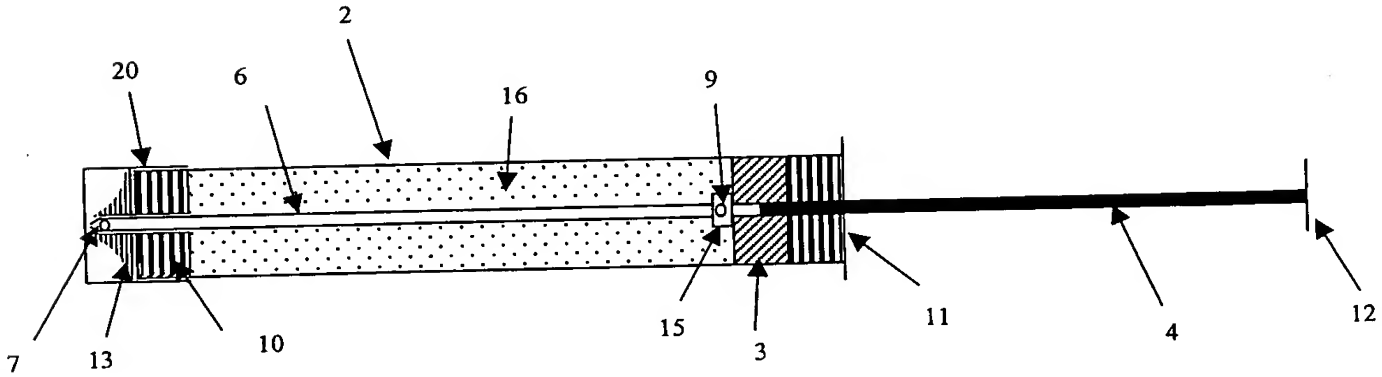

Figure 8